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HENRY, MICHAEL C	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/743,269	Applicant(s) NILSSON, KURT	
	Examiner Michael C. Henry	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-16 and 20-32 is/are pending in the application.
4a) Of the above claim(s) 20-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 10-16, 30-32 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

A request for continued examination is acknowledged. The following office action is a responsive to the Amendment filed, 01/28/08. The amendment filed 01/28/08 affects the application, 10/743,269 as follows:

1. Claims 10 and 30 have been amended. Applicant's amendment have overcome the 102, 102/103 rejections made over the Bergami et al.'s reference. However, a new ground of rejection is present herein.
2. The responsive to applicants' amendments is contained herein below.

Claims 10-16, 20-32 are pending in application

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 10-16, 30-32 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1, 18-30 of U.S. Patent No. 6,686,457 B1. Although

the conflicting claims are not identical, they are not patentably distinct from each other because both inventions are directed to a composition comprising : a saccharide coupled to a spacer; and a matrix coupled to the spacer; wherein the spacer comprises a specific formula.

Claim 10 is drawn to a composition comprising: a saccharide coupled to a spacer; and a matrix coupled to the spacer; the matrix being a cross-linked agarose, wherein the spacer comprises the following formula: $-\text{O}(\text{CH}_2)_n\text{PhNH}-$, or $-\text{N}(\text{Ac})-(\text{CH}_2)_n\text{NH}-$, wherein n is an integer selected from 0, 1, 2, 3, 4, 5, 6, or 7. Claim 11 is drawn to said composition, further comprising a second spacer attached to the matrix. Claim 13 is drawn to said composition comprising specific mmole of bound saccharide per liter of matrix. Claim 14 is drawn to said composition comprising specific blood group A and B determinants bound to the matrix. Claims 15, 16, are drawn to said composition wherein the saccharide binds specific organisms or substances and wherein the spacer is of specific structure. Claim 31 is drawn to said composition of claim 10 wherein the composition (filtration material) is in the form of particles. Claim 30 is drawn to a composition comprising: a saccharide coupled to a spacer; and a matrix coupled to the spacer; wherein the spacer comprises the following formula: $-\text{O}(\text{CH}_2)_n\text{PhNH}-$, or $-\text{N}(\text{Ac})-(\text{CH}_2)_n\text{NH}-$, wherein n is an integer selected from 0, 1, 2, 3, 4, 5, 6, or 7 and wherein the bound saccharide is of specific mmole per liter of matrix. Claim 32 is drawn to said composition of claim 30 wherein the composition (filtration material) is in the form of particles.

Claim 1 of Nilsson et al. is drawn to a composition comprising: a saccharide-spacer-matrix coupled to the spacer; wherein the spacer has a specific formula. Claims 20-25, 27-30 are drawn to said composition comprising blood group determinants A and B, wherein the saccharide binds specific organisms or substances and wherein the spacer is of specific structure.

The difference between applicant's claimed method and the method of Nilsson et al. is that applicant composition contains other spacers in addition to the spacer $O(CH_2)_nPhNH-$ and the blood group determinants A and B disclosed by Nilsson et al. However, it is obvious to a skilled artisan to prepare Nilsson et al.'s composition comprising the spacer and blood group determinants A and B disclosed by Nilsson et al. ($O(CH_2)_nPhNH-$) and other similar compositions comprising similar spacers and blood group determinants that have the same utility as Nilsson et al.'s composition.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to prepare Nilsson et al.'s composition comprising the spacer disclosed by Nilsson et al. ($O(CH_2)_nPhNH-$) and other similar compositions comprising similar spacers and blood group determinants that have the same utility as Nilsson et al.'s composition.

One having ordinary skill in the art would have been motivated to prepare Nilsson et al.'s composition comprising the spacer disclosed by Nilsson et al. ($O(CH_2)_nPhNH-$) and other similar compositions comprising similar spacers and blood group determinants in order to use them to treat blood.

Claims 10, 30-32 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1-3 of U.S. Patent No. 6,444,655 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because both inventions are directed to a composition comprising : a saccharide coupled to a spacer; and a matrix coupled to the spacer; wherein the spacer comprises a specific formula.

Claim 10 is drawn to a composition comprising: a saccharide coupled to a spacer; and a matrix coupled to the spacer; the matrix being a cross-linked agarose, wherein the spacer

comprises the following formula: $-\text{O}(\text{CH}_2)_n\text{PhNH}-$, or $-\text{N}(\text{Ac})-(\text{CH}_2)_n\text{NH}-$, wherein n is an integer selected from 0, 1, 2, 3, 4, 5, 6, or 7. Claim 11 is drawn said composition, further comprising a second spacer attached to the matrix. Claim 13 is drawn to said composition comprising specific mmole of bound saccharide per liter of matrix. Claim 14 is drawn to said composition comprising specific blood group A and B determinants bound to the matrix. Claim 31 is drawn to said composition of claim 10 wherein the composition (filtration material) is in the form of particles. Claim 30 is drawn to a composition comprising: a saccharide coupled to a spacer; and a matrix coupled to the spacer; wherein the spacer comprises the following formula: $-\text{O}(\text{CH}_2)_n\text{PhNH}-$, or $-\text{N}(\text{Ac})-(\text{CH}_2)_n\text{NH}-$, wherein n is an integer selected from 0, 1, 2, 3, 4, 5, 6, or 7 and wherein the bound saccharide is of specific mmole per liter of matrix. Claim 32 is drawn to said composition of claim 30 wherein the composition (filtration material) is in the form of particles

Claim 1 of Nilsson et al. is drawn to a composition comprising: a saccharide-spacer-matrix coupled to the spacer; wherein the spacer is $-\text{O-Et-PhNH-CO}(\text{CH}_2)_5\text{NH-CH}_2\text{-CH}(\text{OH})\text{-CH}_2\text{-O-}$ (i.e., it comprises $-\text{O}(\text{CH}_2)_n\text{PhNH-}$ wherein $n=2$), and the matrix is a cross-linked agarose (i.e., Sepharose® 4 FF).

The difference between applicant's claimed method and the method of Nilsson et al. is that applicant composition contains other spacers in addition to the spacer $-\text{O}(\text{CH}_2)_n\text{PhNH-}$. However, it is obvious to a skilled artisan to prepare Nilsson et al.'s composition comprising the spacer disclosed by Nilsson et al. $-\text{O}(\text{CH}_2)_n\text{PhNH-}$ and other similar compositions comprising similar spacers that have the same utility as Nilsson et al.'s composition.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to prepare Nilsson et al.'s composition comprising the spacer disclosed by Nilsson et al. $(-\text{O}(\text{CH}_2)_n\text{PhNH}-)$ and other similar compositions comprising similar spacers that have the same utility as Nilsson et al.'s composition.

One having ordinary skill in the art would have been motivated to prepare Nilsson et al.'s composition comprising the spacer disclosed by Nilsson et al. $(-\text{O}(\text{CH}_2)_n\text{PhNH}-)$ and other similar compositions comprising similar spacers in order to use them to treat blood.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 10 is rejected under 35 U.S.C. 102(b) as being anticipated by Lisman et al. (Hoppe-Seyler's Zeitschrift fuer Physiologische Chemie (1978), 359 (8), 1019-22, Abstract only).

Claim 10 is drawn to a composition comprising: a saccharide coupled to a spacer; and a matrix coupled to the spacer; the matrix being a cross-linked agarose, wherein the spacer comprises the following formula: $-\text{O}(\text{CH}_2)_n\text{PhNH}-$, or $-\text{N}(\text{Ac})-(\text{CH}_2)_n\text{NH}-$, wherein n is an integer selected from 0, 1, 2, 3, 4, 5, 6, or 7. Lisman et al. discloses applicant's composition comprising: a saccharide (monoosaccharide) coupled to a spacer; and a matrix coupled to the spacer; the matrix being a cross-linked agarose (sepharose), wherein the spacer comprises the following formula: $-\text{OPhNH}-$, wherein n is 0 (see abstract). It should be noted the O in the

spacer is oxygen atom that attaches to the monosaccharide and N in the spacer is nitrogen atom that attaches to the cross-linked agarose (sepharose) (see abstract). Lisman et al. refers to the composition as sepharose-p-aminophenyl-2-acetamido-2-deoxy- β -D-glycopyranoside (see abstract).

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 30-32 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lisman et al. (Hoppe-Seyler's Zeitschrift fuer Physiologische Chemie (1978), 359 (8), 1019-22, Abstract only).

Claim 30 is drawn to a composition comprising: a saccharide coupled to a spacer; and a matrix coupled to the spacer; wherein the spacer comprises the following formula: -
(CH₂)_nPhNH-, or -N(Ac)-(CH₂)_nNH-, wherein n is an integer selected from 0, 1, 2, 3, 4, 5, 6, or 7 and wherein the bound saccharide is of specific mmole per liter of matrix. Claims 31 and 32 are drawn to said composition wherein the composition is in the form of particles.

Lisman et al. discloses applicant's composition comprising: a saccharide (monoosaccharide) coupled to a spacer; and a matrix coupled to the spacer; the matrix being a cross-linked agarose (sepharose), wherein the spacer comprises the following formula: $-\text{OPhNH}-$, wherein n is 0 (see abstract). It should be noted the O in the spacer is oxygen atom that attaches to the monosaccharide and N in the spacer is nitrogen atom that attaches to the cross-linked agarose (sepharose) (see abstract). Lisman et al. refer to the composition as sepharose-p-aminophenyl-2-acetamido-2-deoxy- β -D-glycopyranoside (see abstract).

Furthermore, it should be noted that Lisman et al. is silent about the amount of saccharide (monosaccharide) bound to the matrix (see abstract). But, the silence of Lisman et al. do not mean that the amount of oligosaccharide bound is not the same as that claimed by applicant. Lisman et al. anticipates the claims if their composition has the same amount of bound saccharide (monosaccharide) as applicant's composition and Lisman et al. render the claims as being obvious if the limitations of their composition that pertains to the amount of bound saccharide (monosaccharide) are substantially close to the recited limitations of applicant's claimed composition. Claims 31 and 32 are also encompassed by this rejection since the silence of Lisman et al. about the composition being in particle form does not mean that it is not in said particle form.

Response to Arguments

Applicant's arguments with respect to the 102, 102/103 of claims 10 and 30-32 have been considered but are moot in view of the new ground(s) of rejection. The double patenting rejections are maintained.

Conclusion


Application/Control Number:
10/743,269
Art Unit: 1623

Page 9

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry


Shaojia Anna Jiang, Ph.D.
Supervisory Patent Examiner
Art Unit 1623

February 1, 2008.